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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,493	09/28/2001	Joseph Luber	MCP-0274	5286

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/966,493	LUBER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15 and 17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-15 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected because they do not identify the structure, material, or acts set forth in the specification that would be capable of carrying out the functional properties recited in the claims. It appears from the specification that the claimed release rate is achieved from formulations that contain a specific structure, such as a specific wax in a specific amount (see examples 1-4). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, the structure which makes up the formulation must be clearly and positively specified.

Claims 1, 3-15 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims lack the description of the possible genus with the recited functional characteristics. Furthermore, the claims recite an immediate release rate by 30 minutes in pH 5.8 buffer, however, the specification also discloses a similar immediate release rate by 15 minutes in pH 5.8 buffer. Therefore, it is not clear from the specification when and how the tablet can exhibit similar release rates at two different time, 15 minutes and 30 minutes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. 6,194,000, or Harbit 3,108,046, in view of Joshi et al. US 5,030,447 and Sharma et al. US 4,894,234.

Smith teaches an analgesic composition comprising immediate and controlled release forms (see abstract). The immediate release comprises up to 90% of the analgesic agent, polyethylene glycol, waxes, and other carriers (column 2, lines 39-50; and column 3, lines 29-51). The dosage form provides from about 1-5000 mg/day of the analgesic agent (ID). The composition is in for oral administration in tablet or

capsule or granule form (column 2, lines 55-67). Suitable coating to provide sustained release comprises cellulose derivatives polymer (column 4, lines 26-45).

Harbit teaches a high dose tablet comprising from about 75% to about 98% drug and wax, such as paraffin wax or shellac wax (column 3, lines 1-31). The tablet dosage further comprises lubricant (column 4, lines 9-19). The dosage form provides both immediate release and sustained release (column 4, lines 21-31).

Smith or Harbit does not teach acetaminophen. Sharma teaches analgesic includes acetaminophen (column 5, lines 54-55). Thus, it would have been obvious to prepare an acetaminophen composition in view of the teaching of Sharma, because Sharma teaches analgesic includes acetaminophen, aspirin, or ibuprofen, and because Smith and Harbit teach compositions suitable for analgesic active agents.

Smith or Harbit does not explicitly teach wax in powder form. Joshi teaches a tablet dosage form comprising wax in finely powdered form having size less than 500 μm such as microcrystalline wax, carnauba wax, or paraffin (column 2, lines 22-24). Thus, it would have been obvious to one of ordinary skill in the art to modify the wax in the tablet dosage of Smith or Harbit using the finely powdered wax in view of the teaching of Joshi, because Joshi teaches a composition include one or more powder wax result in an excellent storage stable even thought it includes a medicament which may degrade in a low pH environment (column 1, lines 37-40), because Smith or Harbit teaches the use of wax in tablet dosage form comprising active agents.

Claims 1, 3-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. 6,194,000, or Harbit 3,108,046, in view of Sharma et al. US 4,894,234 and Remon (WO 01/21155 A1) and Mueller et al. US 5,643,984.

Smith or Harbit in view of Sharma are relied upon for the reason stated above. The references do not explicitly teach wax in powder form. Remon discloses a rapidly disintegrating tablet comprising an active agent and wax (page 10, lines 14-18; page 19, lines 10-21). Wax includes microcrystalline wax or a natural wax (page 11, line 7 through page 15, line 8). The composition further contains disintegrants, swellable materials as well as other fillers (page 15, line 9 - page 18, line 6). Active agents are chosen from a wide variety of known pharmaceutical agents (page 19, line 22 - page 20, line 18). The composition also includes a film coating (page 21, line 4 - page 22, line 8). The tablets are produced by compression (page 23, lines 3-9). The tablets are rapid disintegration tablets (page 24, line 16 - page 25, line 1).

Remon does not expressly teach the particle size of the microcrystalline wax. Mueller teaches typical microcrystalline hydrocarbon waxes having particle size within the range of about 1 μm to about 300 μm (column 2, lines 55-65). Thus, it would have been obvious for one of ordinary skill in the art to use microcrystalline wax in view of the teachings of Remon and Mueller for the composition taught by Smith or Harbit, because Remon teaches the use of wax in tablet dosage form that disintegrate rapidly in water (page 9, lines 5-10), because Smith or Harbit teaches the use of wax in tablet dosage form, and because Mueller teaches microcrystalline wax having particle size within the claimed range is known and typical.

It is noted that the cited references do not teach the claimed release rate by 30 minutes in pH 5.8 buffer. However, it is the position of the examiner that the tablets taught by the cited references would exhibit the claimed release rates because Harbit or Smith in combination with the secondary references teach the use of similar ingredients, including powder wax, such as microcrystalline wax.

Response to Arguments

Applicant's arguments filed 10/02/06 have been fully considered but they are not persuasive.

Applicant argues that Smith and Harbit teach tablets that are exhibit combination of immediate and sustained releases. It is not seen where that any of these cited documents disclose or suggest tablets that are immediate release alone. In response to applicant's arguments, it is noted that the present claims do not preclude the sustained release taught in the prior arts.

Applicant argues that the cited references do not teach the release rate by 30 minutes in pH 5.8 buffer. However, the burden is shifted to applicant to show that the tablets taught by Smith and Harbit in combination with Joshi or Remon do not have the claimed release properties. This is because the cited references teach immediate release tablets using the claimed wax, such as microcrystalline wax.

Applicant argues that Remon does not teach wax particles. In view of applicant's argument, Remon is cited in combination of Mueller for the teaching of microcrystalline wax having the claimed particle size.

Applicant argues that one of ordinary skill in the art would not look to the disclosure of ink compositions of Mueller to find motivation in selecting the particle size of wax to be used in a swallowable immediate release tablet. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is known to the skilled in the art that the term "microcrystalline" means crystalline having particle diameter that is abnormally small, that is visible only under the microscope (in micron size) (see Webster II dictionary). Mueller is relied upon solely for the teaching that typically, microcrystalline wax has particle size from about 1 micron to about 300 microns.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

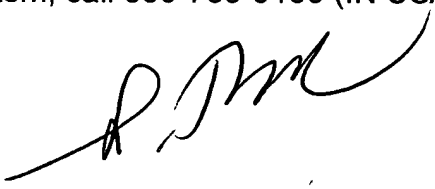
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran
Examiner
Art Unit 1615